5 Rec'd PCT/PTO 13 JUN 2006

Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. TRANSMITTAL LETTER TO THE UNITED STATES ATTORNEY'S DOCKET NUMBER LP-31004-US DESIGNATED/ELECTED OFFICE (DO/EO/US) U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/569862 **CONCERNING A SUBMISSION UNDER 35 U.S.C. 371** INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE 30 August 2004 PRIORITY DATE CLAIMED 29 August 2003 PCT/DK2004/000573 TITLE OF INVENTION MODIFIED RELEASE COMPOSITIONS COMPRISING TACROLIMUS APPLICANT(S) FOR DO/EO/US HOLM et al. Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). h has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). b. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). a h. have been communicated by the International Bureau. C. have not been made; however, the time limit for making such amendments has NOT expired. d. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. A preliminary amendment. An Application Data Sheet under 37 CFR 1,76. 15 A substitute specification. 16. A power of attorney and/or change of address letter. 17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. 18 A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. Other items or information: Unexecuted Declaration and Power of Attorney and International Search Report

his collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mall Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO-1390 (Rev. 02-2005)
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	U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/569862			PCT/DK2004/000573		ATTORNEY'S DOCKET NUMBER		
	The following fees have been submitted					CALCULATIONS	PTO USE ONLY	
	21. Basic national fee			***************************************	\$300		1	
	22. Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions PCT Article 33(1)-(4)					\$		
						\$		
	TOTAL OF 21, 22 and 23 =					\$		
	Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.							
	Total Sheets	Extra Sheets		additional 50 or fraction p to a whole number)	RATE			
	- 100 =	/50 =			× \$250	\$		
	Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).					\$ 130		
	CLAIMS	NUMB	ER FILED	NUMBER EXTRA	RATE	\$		
	Total claims		- 20 =		x \$50	\$		
	Independent clair	ns	- 3 =		× \$200	\$ 0		
	MULTIPLE DEPE	NDENT CLAIM(S) (if applicable)		+ \$360	\$		
	TOTAL OF ABOVE CALCULATIONS =					\$		
	✓ Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.					-\$65		
	SUBTOTAL =					\$ 65		
	Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).					\$		
	TOTAL NATIONAL FEE =					\$ 65		
	Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +					\$		
06/16/2006	06 GFREY1 00000132 10569862 TOTAL FEES ENCLOSED					\$ 65		
01 FC:261						Amount to be refunded:	\$	
						Amount to be charged:	\$	
	a. A check in the amount of \$ to cover the above fees is enclosed.							
			peposit Account No in the amount of \$ to cover the above fees. this sheet is enclosed.					
	c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any ov Account No A duplicate copy of this sheet is enclosed.							
	d. Fees are to be charged to a credit card. WARNING: Information on this form may become public be included on this form. Provide credit card information and authorization on PTO-2038.					lic. Credit card informa	tion should not	
	NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive and granted to restore the International Application to pending status.					(37 CFR 1.137(a) or (b)) must be filed	
	SEND ALL CORRESPONDENCE TO:				Geres Horis			
	Customer No. 25538					<i>U</i> H. Agris	ĺ	
	D . 10	112/116		NAME		i i. Aglia		
	Date: WIJOIV				34,08	86 l		
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	EODM DTO	1390 (REV_02-2005)		Page 2 of 2				

Attorney Docket No.: LP-31004-US

PATENT

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

INTERNATIONAL APPLICATION NO. PCT/DK2004/000573

US APPLN. Ser. NO: 10/569862

INTERNATIONAL FILING DATE: 30 August 2004

PRIORITY DATE: 29 August 2003

TITLE: MO

MODIFIED RELEASE COMPOSITIONS COMPRISING TACROLIMUS

APPLICANT(S) FOR RO/US: HOLM, Per and NORLING, Tomas EXPRESS MAIL CERTIFICATE

Mail Stop PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Express Mail Label No. EV746361340US

Date of Deposit: June 13, 2006

I hereby certify that the following attached paper(s) or fee

- 1. Transmittal Letter to the DO/EO/US
- 2. PTO 2038 (Fee of \$65.00)
- 3. Declaration and Power of Attorney (executed)
- 4. International Search Report
- 5. Information Disclosure Statement
- 6. PTO 1449 Form
- 7. References (9-Foreign Patent Documents and other documents)

are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 C.F.R. 1.10 on the date indicated above and is addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Cheryl H. Agris

(Name of person mailing paper(s) or fee)

(Signature of person mailing paper(s) or fee)

Mailing address: P.O. Box 806, Pelham, N.Y. 10803; telephone: (914) 712-0093